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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,472	07/11/2003	Lijiang Yang	AA-603M	5309

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,472

Applicant(s)

YANG ET AL.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date A and B.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 1 and 4 are indefinite insofar as the basis for determining the weight percentage is not set forth, e.g., percent by weight based on the total weight of the composition, percent by weight based on the weight of the aqueous carriers, etc. See Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.)

2) Claim 1, the recitation of 1 to 50 percent talc (component "(1)"), followed by the subsequent recitation of 5 to 50 percent "abrasive polishing material" (component "(3)") later in the claim, is confusing since no clear line of demarcation is provided between the latter and the former, which is itself already an abrasive. The examiner recommends inserting the word "another" before the term "abrasive" at the fifth line of the claim in order to obviate this ground of rejection.

3) Claim 1, last two lines, the modifying term "about" is indefinite, as explained herein.

Normally, the term "about" is not considered indefinite. In certain specific factual situations in which close prior art exists, however, the courts have recognized that sufficient ambiguity may arise to render the term indefinite. See specifically Amgen v. Chugai, 927 F.2d 1200 (Fed. Cir. 1991), where the court found that the recitation of a specific activity of "about" 160,000 gave no hint as to which value

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between the prior art value of 128,620 and 160,000 constituted infringement and hence was indefinite. As noted at page 1218 of the decision, the holding was further supported by the fact that "nothing in the specification, prosecution history, or prior art provides any indication as to what range of specific activity is covered by the term".

That is the case here. Close prior art exists (USP 4,428,928; see the "Anticipation" section infra), and nothing in the instant specification or prior art provides any indication as to how far the term "about" extends the instantly claimed pH above and below the value of 8 recited at the last line of claim 1. Similarly, it is not clear how far below 30 one can go and still infringe that value as recited at the penultimate line of the claim.

4) Claim 2, the phrase "modified" is a relative term which renders the claim indefinite. In particular, "modified" does not particularly point out the degree or type of modification that a given talc may have in relation to the parent talc and still be considered "modified" as intended by applicants. Applicants have failed to provide any specific definition for this term in the present specification. Lacking a clear meaning of the phrase "modified", the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection. (Only one example of (presumably) a "modified" talc is actually set forth by the instant specification, namely methicone treated talc at p. 2, lines 24).

5) The term "high purity" in claim 2 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,428,928.

The prior art discloses dentifrices comprising at least 10 percent talc (col. 2, line 66), a fluoride salt such as sodium fluoride in an amount sufficient to provide about 1000ppm fluoride ion (col. 9, lines 23-28), and at least 20 percent by weight of calcined kaolin abrasive polishing material (col. 2, line 65). Various conventional additives, e.g., surfactants, humectants, flavors, etc. are used as well: see col. 7 in its entirety, and col. 8 up to line 4. Also disclosed is fumed silica (col. 7, line 21), an abrasive. (The examiner recognizes that it might not be the best of abrasive polishing agents, but any degree of polishing ability, even a minor one, would be sufficient to meet the instant claim limitations for component “(3)” of claim 1 (and thus the silica of claim 9) since no particular degree of abrasiveness is required or specified).

Preferred dentifrice compositions are set forth in working examples VII-IX at cols. 9 and 10. Those compositions contain 24, 27, and 29 parts water, respectively. Because they also contain 24, 23 and 12 percent aqueous sorbitol (70 percent) as well, it is clear that they contain sufficient water to meet the limitations required for instant component “(4)” in claim 1. Those working examples also contain 0.96 percent citric acid, and 0.25 percent sodium citrate dihydrate, respectively, thus meeting the limitations of instant claims 4 and 5.

And finally, the prior clearly states that its fluoride-containing dentifrices have, “naturally”, pH's of up to 8. That “natural” pH may be raised to 9 with a buffering agent as well. (Col. 9, lines 33-37).

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 4,428,928 in view of USP 4,418,053.

This rejection is made in the interest of completeness and presumes, purely *arguendo* and for this particular rejection only, that fumed silica is not an "abrasive polishing material" as required by the instant claim 1.

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The primary reference is discussed in the "Anticipation" rejection supra, and (for the purposes of this rejection) differs from the instant claim insofar as it does not specifically teach incorporating an abrasive silica polishing agent.

The secondary reference discloses dentifrices containing abrasives, including talc and related minerals. See, e.g., col. 6, line 8. It differs from the instant claims insofar as it does not use talc in a discrete embodiment, e.g. a working example or preferred dentifrice composition, and does not disclose a specific pH. The reference does suggest that a portion of the abrasive may be replaced by other different abrasives (polishing agents) including silica, in order to tailor the particular characteristics of the dentifrice to the specific desires of particular users. See col. 11, lines 21-30.

It would have been obvious to have replaced a portion of the abrasive component of the primary reference with another abrasive such as silica, in order to tailor the characteristics of specific dentifrices to particular users as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Fred Krass', written over the printed name.